#### **REMARKS/ARGUMENTS**

This is a preliminary amendment in a RCE Application. The Office Action mailed March 22, 2004 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested. The claims presented for examination are: claims 10-28. Claims 1-9 stand withdrawn.

### 35 USC 112 Rejection

In numbered paragraph 4 of the Office Action mailed March 22, 2004, claims 10-28 were rejected under 35 USC 112, second paragraph as being indefinite.

In numbered paragraph 5 of the Office Action mailed March 22, 2004, claims 10, 16, and 24 were rejected under 35 USC 112, second paragraph as being incomplete for omitting essential structural cooperative relationships of elements.

Claims 10, 16, and 24 have been amended in response to the 35 USC 112 rejection. The claims now clarify the structural cooperative relationships of elements by specifying that "beads coated with antibodies located in said space between said electrodes wherein said beads coated with antibodies stick to the pathogens" and that "said beads coated with antibodies amplifying the change in impedance." Applicants believe the amended claims 10, 16, and 24 comply with the requirements of 35 USC 112.

35 USC 103 Rejection - Van Gerwen et al in View of Nelson et al
In numbered paragraph 9 of the Office Action mailed March 22, 2004,
claims 10, 12-18, and 21-28 were rejected under 35 U.S.C. 103(a) as allegedly
unpatentable over the Van Gerwen et al reference (WO 97/21094) in view of the

Nelson et al reference (U.S. Patent 6,074,827).

Applicants have amended all of the independent claims in the application, claims 10, 16, and 24. Applicants respectfully submit that the amended independent claims 10, 16, and 24 are patentable.

The factual inquiries set forth in <u>Graham v. John Deere Co.</u>, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Van Gerwen et al reference and Applicants' invention defined by amended claims 10, 16, and 24 include the fact that the following elements of amended claims 10, 16, and 24 are not found in the primary Van Gerwen et al reference:

"beads coated with antibodies located in said space between said electrodes wherein said beads coated with antibodies stick to the pathogens," or

"an impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance."

While the Nelson et al reference discloses "beads," the Nelson et al reference does not show beads in "an apparatus including means for determining trapping of pathogens carried by a fluid by antibodies deposited in a fluidic channel," or "a fluidic channel having at least one pair of spaced electrodes having surfaces and with a space between said electrodes, said electrodes localized along a length of said fluidic channel, with the electrodes of said at least one pair being located on the same side of said fluidic channel, antibodies immobilized on said surfaces of said spaced electrodes and immobilized in said space between said electrodes wherein said pathogens

carried by said fluid attach to said immobilized antibodies, means for producing an electric field across said spaced electrodes, and an impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance."

Further, there is no suggestion or motivation to combine the primary Van Gerwen et al reference and the secondary Nelson et al reference. Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since there is no suggestion or motivation to combine the Van Gerwen et al and the Nelson et al references to produce Applicant's invention, a 35 USC §103(a) rejection of Applicant's amended independent claims 10, 16, and 24 would not be appropriate.

Applicants respectfully submit that the independent claims, claims 10, 12-18, and 21-28 are patentable and since the other claims depend from the independent claims, all the claims presented for examination are patentable.

35 USC 103 Rejection - Clark et al, Kipling et al, and Nelson et al
In numbered paragraph 10 of the Office Action mailed March 22, 2004,
claims 10, 12-13, 16, and 20-26 were rejected under 35 U.S.C. 103(a) as allegedly
unpatentable over the Clark et al reference (U.S. Pat. 5,194,133) in view of the
Kipling et al Reference (U.S. Pat. 5,374,521) and Nelson et al reference (U.S.
Patent 6,074,827).

Applicants have amended all of the independent claims in the application, claims 10, 16, and 24. Applicants respectfully submit that the amended independent claims 10, 16, and 24 are patentable.

The factual inquiries set forth in <u>Graham v. John Deere Co.</u>, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Clark et al reference and Applicants' invention defined by amended independent claims 10, 16, and 24 include the fact that the following elements of amended independent claims 10, 16, and 24 are not found in the primary Clark et al reference:

"beads coated with antibodies located in said space between said electrodes wherein said beads coated with antibodies stick to the pathogens," or

"an impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance."

The Nelson et al reference does not show beads in "an apparatus including means for determining trapping of pathogens carried by a fluid by antibodies deposited in a fluidic channel," or "antibodies immobilized on said surfaces of said spaced electrodes and immobilized in said space between said electrodes wherein said pathogens carried by said fluid attach to said immobilized antibodies, a fluidic channel having at least one pair of spaced electrodes having surfaces and with a space between said electrodes, said electrodes localized along a length of said fluidic channel, with the electrodes of said at least one pair being located on the same side of said fluidic channel,

antibodies immobilized on said surfaces of said spaced electrodes and immobilized in said space between said electrodes wherein said pathogens carried by said fluid attach to said immobilized antibodies, means for producing an electric field across said spaced electrodes, and an impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance."

Further, there is no suggestion or motivation to combine the primary Clark et al reference, the secondary Kipling et al reference and the tertiary Nelson et al reference. Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since there is no suggestion or motivation to combine the Clark et al reference, the secondary Kipling et al reference and the tertiary Nelson et al references to produce Applicant's invention, a 35 USC §103(a) rejection of Applicant's amended independent claims 10, 16, and 24 would not be appropriate. Applicants respectfully submit that the independent claims, claims 10, 12-18, and 21-28 are patentable and since the other claims depend from the independent claims, all the claims presented for examination are patentable.

35 USC 103 Rejection - Clark et al, Kipling et al, Nelson et al and Taylor et

<u>al</u>

In numbered paragraph 11 of the Office Action mailed March 22, 2004, claims 11, 14, 17-19, and 27-28 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over the Clark et al reference (U.S. Pat. 5,194,133) in view of the Kipling et al reference (U.S. Pat. 5,374,521), further in view of the Nelson et al reference, and further in view of the Taylor et al (U.S. Pat. 5,001,048) reference.

Applicants have amended independent claims 10, 16, and 24 and therefore have amended claims 11, 14, 17-19, and 27-28. Applicants respectfully submit that claims 11, 14, 17-19, and 27-28 are patentable over the Clark et al reference, the Kipling et al reference, the Nelson et al reference, and the Taylor et al reference and any legitimate combination of the references.

The factual inquiries set forth in <u>Graham v. John Deere Co.</u>, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Clark et al reference and Applicants' invention defined by amended independent claims 10, 16, and 24 include the fact that the following elements of amended independent claims 10, 16, and 24 are not found in the primary Clark et al reference:

"beads coated with antibodies located in said space between said electrodes wherein said beads coated with antibodies stick to the pathogens," or

"an impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance."

The Nelson et al reference does not show beads in "an apparatus including means for determining trapping of pathogens carried by a fluid by

antibodies deposited in a fluidic channel," or "antibodies immobilized on said surfaces of said spaced electrodes and immobilized in said space between said electrodes wherein said pathogens carried by said fluid attach to said immobilized antibodies, a fluidic channel having at least one pair of spaced electrodes having surfaces and with a space between said electrodes, said electrodes localized along a length of said fluidic channel, with the electrodes of said at least one pair being located on the same side of said fluidic channel, antibodies immobilized on said surfaces of said spaced electrodes and immobilized in said space between said electrodes wherein said pathogens carried by said fluid attach to said immobilized antibodies, means for producing an electric field across said spaced electrodes, and an impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance."

Further, there is no suggestion or motivation to combine the primary Clark et al reference, the secondary Kipling et al reference and the tertiary Nelson et al reference. Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since there is no suggestion or motivation to combine the Clark et al, Kipling et al, Nelson et al and Taylor et al references to produce Applicant's invention, a 35 USC §103(a) rejection of Applicant's amended independent claims 10, 16, and 24 would not be

appropriate. Applicants respectfully submit that the independent claims, claims 10, 12-18, and 21-28 are patentable and since the other claims depend from the independent claims, all the claims presented for examination are patentable.

35 USC 103 Rejection - Clark et al, Kipling et al, Nelson et al and Stetter et al

In numbered paragraph 12 of the Office Action mailed March 22, 2004, claim 15 was rejected under 35 U.S.C. 103(a) as allegedly unpatentable over the Clark et al reference (U.S. Pat. 5,194,133), in view of the Kipling et al reference (U.S. Pat. 5,374,521), and the Nelson et al reference, further in view of the Stetter et al reference (U.S. Pat. 5,567,301).

Applicants have amended claim 15 by amending its parent claim 10.

Applicants respectfully submit that claims 10 is patentable over the Clark et al reference, the Kipling et al reference, the Nelson et al reference, and the Taylor et al reference and any legitimate combination of the references.

The factual inquiries set forth in <u>Graham v. John Deere Co.</u>, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Clark et al reference and Applicants' invention defined by amended independent claim 10 includes the fact that the following elements of amended independent claim 10 is not found in the primary Clark et al reference:

"beads coated with antibodies located in said space between said electrodes wherein said beads coated with antibodies stick to the pathogens," or

"an impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance."

The Kipling et al, Nelson et al, and Setter et al references do not show beads in "an apparatus including means for determining trapping of pathogens carried by a fluid by antibodies deposited in a fluidic channel," or "antibodies immobilized on said surfaces of said spaced electrodes and immobilized in said space between said electrodes wherein said pathogens carried by said fluid attach to said immobilized antibodies, a fluidic channel having at least one pair of spaced electrodes having surfaces and with a space between said electrodes, said electrodes localized along a length of said fluidic channel, with the electrodes of said at least one pair being located on the same side of said fluidic channel, antibodies immobilized on said surfaces of said spaced electrodes and immobilized in said space between said electrodes wherein said pathogens carried by said fluid attach to said immobilized antibodies, means for producing an electric field across said spaced electrodes, and an impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance."

Further, there is no suggestion or motivation to combine the primary Clark et al reference with the Kipling et al reference and the Nelson et al reference and the Setter et al reference. Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's

disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since there is no suggestion or motivation to combine the Clark et al, Kipling et al, Nelson et al and Setter et al references to produce Applicant's invention, a 35 USC §103(a) rejection of Applicant's amended independent claim 10 would not be appropriate. Applicants respectfully submit that the independent claim 10 is patentable and since claim 15 depends from independent claim 10, claim 15 presented for examination is patentable.

35 USC 103 Rejection – Van Gerwen et al in View of Taylor et al.

In numbered paragraph 13 of the Office Action mailed March 22, 2004, claims 11 and 19 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over the Van Gerwen et al reference (WO 97/21094) and Nelson et al reference, in view of the Taylor et al reference (U.S. Pat. 5,374,521).

Applicants have amended claim 10 and therefore dependent claims 11 and 19. Applicants respectfully submits that amended claim 10 and dependent claims 11 and 19 are patentable over the Van Gerwen et al, Nelson et al, and Taylor et al references and any legitimate combination of the references.

The factual inquiries set forth in <u>Graham v. John Deere Co.</u>, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Van Gerwen et al reference and Applicants' invention defined by amended independent claim 10 includes the fact that the following elements of amended independent claim 10 is not found in the primary Van Gerwen et al reference:

"beads coated with antibodies located in said space between said electrodes wherein said beads coated with antibodies stick to the pathogens," or "an impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance."

The Nelson et al and Taylor et al references do not show beads in "an apparatus including means for determining trapping of pathogens carried by a fluid by antibodies deposited in a fluidic channel," or "antibodies immobilized on said surfaces of said spaced electrodes and immobilized in said space between said electrodes wherein said pathogens carried by said fluid attach to said immobilized antibodies, a fluidic channel having at least one pair of spaced electrodes having surfaces and with a space between said electrodes, said electrodes localized along a length of said fluidic channel, with the electrodes of said at least one pair being located on the same side of said fluidic channel, antibodies immobilized on said surfaces of said spaced electrodes and immobilized in said space between said electrodes wherein said pathogens carried by said fluid attach to said immobilized antibodies, means for producing an electric field across said spaced electrodes, and an impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance."

Further, there is no suggestion or motivation to combine the primary Van Gerwen et al reference, the Nelson et al reference, and the Taylor et al reference. Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It

should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Since there is no suggestion or motivation to combine the Van Gerwen et al, Nelson et al, and Taylor et al references to produce Applicant's invention, a 35 USC §103(a) rejection of Applicant's amended independent claim 10 would not be appropriate. Applicants respectfully submit that the independent claim 10 is patentable and since claims 11 and 19 depend from independent claim 10, claims 11 and 19 presented for examination are patentable.

35 USC 103 Rejection –Krulevitch et al, Kipling et al, and Nelson et al In numbered paragraph 14 of the Office Action mailed March 22, 2004, claims 10-28 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over the Krulevitch et al reference, (U.S. Patent 6,437,551), in view of the Kipling et al reference (U.S. Patent 5,374,521) and the Nelson et al reference (U.S. Patent 6,074,827).

The Krulevitch et al reference, (U.S. Patent 6,437,551) and the subject patent application are both owned by the Regents of the University of California as evidenced by assignments recorded in the United States Patent and Trademark Office. The Krulevitch et al reference (U.S. Patent 6,437,551) on its face shows that it is assigned to and owned by the Regents of the University of California. The subject application is also owned by the Regents of the University of California. On December 14, 2000 an assignment was filed in the subject application showing that the subject application is owned by the Regents of the University of California.

A terminal disclaimer in compliance with 37 CFR §321(c) in the form of a DECLARATION UNDER 37 CFR §1.130(b), disclaiming the terminal portion of

any patent granted on the subject application beyond the expiration date of any patent issued upon U.S. Patent 6,437,551 (the Krulevitch et al reference) is enclosed.

Applicants believe this overcomes the rejection of claims 10-28 under 35 U.S.C. 103(a) as allegedly unpatentable over the (U.S. Patent 6,437,551), in view of the Kipling et al reference (U.S. Patent 5,374,521).

## **Double Patenting Rejection - Copending Application**

In numbered paragraph 16 of the Office Action mailed March 22, 2004 claims 10-28 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 10-21 of copending U.S. Application No. 09/993,870 (US 2002/0150886).

United States Application No. 09/993,870 (US 2002/0150886) and the subject patent application are both owned by the Regents of the University of California as evidenced by assignments recorded in the United States Patent and Trademark Office. United States Application No. 09/993,870 (US 2002/0150886) on its face shows that it is assigned to and owned by the Regents of the University of California. The subject application is also owned by the Regents of the University of California. On December 14, 2000 an assignment was filed in the subject application showing that the subject application is owned by the Regents of the University of California.

A terminal disclaimer in compliance with 37 CFR §321(c) in the form of a DECLARATION UNDER 37 CFR §1.130(b), disclaiming the terminal portion of any patent granted on the subject application beyond the expiration date of any patent issued upon U.S. Application No. 09/993,870 (US 2002/0150886) is enclosed.

# Double Patenting Rejection - Copending Application

In numbered paragraph 17 of the Office Action mailed March 22, 2004 claims 10-28 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 10-21 of copending U.S. Application No. 09/738,927 (US 2002/0070114) in view of Kipling et al (U.S. Pat. 5,374,521).

United States Application No. 09/738,927 (U.S. 2002/0070114) and the subject patent application are both owned by the Regents of the University of California as evidenced by assignments recorded in the United States Patent and Trademark Office. 09/738,927 (U.S. 2002/0070114) on its face shows that it is assigned to and owned by the Regents of the University of California. The subject application is also owned by the Regents of the University of California. On December 14, 2000 an assignment was filed in the subject application showing that the subject application is owned by the Regents of the University of California.

A terminal disclaimer in compliance with 37 CFR §321(c) in the form of a DECLARATION UNDER 37 CFR §1.130(b), disclaiming the terminal portion of any patent granted on the subject application beyond the expiration date of any patent issued upon "U.S. Application No. 09/738,927 (US 2002/0070114) is enclosed.

# Double Patenting Rejection - U.S. Patent No. 6,437,551

In numbered paragraph 18 of the Office Action mailed March 22, 2004 claims 10-28 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-22 of U.S. Patent No. 6,437,551 in view of Kipling et al (U.S. Pat. 5,374,521) and Nelson et al (U.S. Patent 6,074,827).

U.S. Patent 6,437,551 and the subject patent application are both owned by the Regents of the University of California as evidenced by assignments recorded in the United States Patent and Trademark Office. U.S. Patent 6,437,551 on its face shows that it is assigned to and owned by the Regents of the University of California. The subject application is also owned by the Regents of the University of California. On December 14, 2000 an assignment was filed in the subject application showing that the subject application is owned by the Regents of the University of California.

A terminal disclaimer in compliance with 37 CFR §321(c) in the form of a DECLARATION UNDER 37 CFR §1.130(b), disclaiming the terminal portion of any patent granted on the subject application beyond the expiration date of any patent issued upon U.S. Patent 6,437,551 is enclosed.

Application No.: 09/737,542

## **SUMMARY**

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated March 22, 2004 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,

Eddie E. Scott

Attorney for Applicant Registration No. 25,220

Tel. No. (925) 424-6897

Livermore, California
Dated: (Lare 11) 2004